

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON, DC/SILVER SPRING
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND

AUGUST 11, 2009

AGENDA

The committee will discuss a new drug application (NDA) for a radiopharmaceutical proposed for a special type of brain imaging in patients with movement disorders. NDA 22-454, Ioflupane I 123 Injection (proposed trade name DaTSCAN), GE HealthCare, is proposed for detecting loss of functional nigrostriatal dopaminergic neurons by single photon emission computed tomography (SPECT) imaging in patients presenting with symptoms or signs of dopaminergic neurodegeneration.

8:00 a.m.	Call to Order and Opening Remarks	Britt Anderson, M.D., Ph.D. Acting Chair Peripheral and Central Nervous System Drugs Advisory Committee
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Introduction of Committee

Conflict of Interest Statement	Diem-Kieu H. Ngo, Pharm.D., BCPS Designated Federal Official
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8:15 a.m.	FDA Introductory Remarks	CAPT Rafel Dwaine Rieves, M.D. Director, Division of Medical Imaging and Hematology Products (DMIHP), Office of Oncology Drug Products (OODP), OND, CDER, FDA
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GUEST SPEAKER PRESENTATIONS

8:30 a.m.	Neurodegeneration in Parkinson's Disease	Ted Dawson, M.D., Ph.D. Director, Movement Disorders Center Johns Hopkins Hospital, Department of Neurology Leonard and Madlyn Abramson Professor of Neurodegenerative Diseases Johns Hopkins University, Institute for Cell Engineering
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9:00 a.m.	Neuroimaging of Dopaminergic Neurons: Evidence for Clinical Utility	Joel S. Perlmutter, M.D. Elliot Stein Family Professor of Neurology Professor of Radiology, Neurobiology, Occupational Therapy, and Physical Therapy Washington University in St. Louis
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AGENDA
-CONTINUED-

INDUSTRY PRESENTATION

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| 9:30 a.m. | Introduction | David Brooks, M.D., D.Sc.
Head of Neurology in Clinical Development, GE Healthcare
Hartnett Professor of Neurology
Imperial College London |
| 9:45 a.m. | Clinical Development Program | Paul Sherwin, M.D., Ph.D.
Senior Director of Clinical Research, GE Healthcare |

10:15 a.m. **BREAK**

INDUSTRY PRESENTATION (CONTINUED)

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| 10:30 a.m. | Clinical Utility of DaT Imaging | Donald Grosset, M.D.
Honorary Senior Lecturer, Glasgow University
Consultant Neurologist, Institute of Neurological Sciences Southern General Hospital, Glasgow, Scotland |
| 10:50 a.m. | Medical Need and Rationale for DaTSCAN in the USA | Mark Stacy, M.D.
Associate Professor
Duke University Movement Disorders Center
Durham, North Carolina |
| 11:05 a.m. | Concluding Statements | David Brooks, M.D., D.Sc. |
| 11:15 a.m. | Clarifying Questions | |

FDA PRESENTATION

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| 11:30 a.m. | NDA Overview | Phillip Davis, M.D.
Medical Officer, DMIHP, OODP, OND, CDER, FDA |
| 11:50 a.m. | Statistical Review of Efficacy | Mark Levenson, Ph.D.
Statistical Reviewer, Office of Biostatistics
Office of Translational Sciences, CDER, FDA |

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12:00 p.m.	Clarifying Questions
12:15 p.m.	LUNCH
1:15 p.m.	Open Public Hearing
2:15 p.m.	Panel Discussion/Committee Questions
3:00 p.m.	BREAK
3:15 p.m.	Panel Discussion/Committee Questions, Continued
5:00 p.m.	ADJOURNMENT